K010374

SonoSite
Imagine What You Can Do

FEB 21 2001

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

Michael A. Hoffman
Director - Regulatory Affairs and Quality Systems
SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

(425) 951 – 1297

E-mail: michael.hoffman@sonosite.com

Date prepared: January 26, 2001

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

SonoSite™ Hand-Carried Ultrasound System (subject to change)

Classification Names

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that the SonoSite™ Hand-Carried Ultrasound System is substantially equivalent to the previously cleared SonoSite™ Hand-Carried Ultrasound System (K003399) and the Advanced Technology Laboratories (ATL) HDI® 5000 Ultrasound System (K961459).

4) Device Description:

The SonoSite™ Hand-Carried Ultrasound System is a highly portable, software-controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and display it on a monitor in 2D, Pulsed Wave (PW) Doppler, Color Power Doppler, PowerMap™ Directional Color Power Doppler, or in a combination of modes.

The System has an electrocardiography (ECG) display feature and supports a 3-lead ECG cable assembly to collect data. The SonoSite™ Hand-Carried Ultrasound System also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used for clinical diagnostic purposes.

The SonoSite™ Hand-Carried Ultrasound System is designed to accept curved or linear transducers of the types and frequency listed in the table below. All actions affecting the performance of the transducer are activated from the main system control panel.

Frequency Range:	2.0 - 10.0 MHz
Transducer Types:	Linear array Curved array Intracavitary array

The SonoSite™ Hand-Carried Ultrasound System is designed to comply with the standards listed below.

EN 60601-1:1997	IEC 61000-4-2:1999
EN 60601-1-1:1993	IEC 61000-4-3:1997
EN 60601-1-2:1998	IEC 61000-4-4:1995
UL 2601-1:1999	IEC 61000-4-5:1999
CAN/CSA C22.2, No. 601.1:1998	ISO 10993
CEI/IEC 61157:1992	ISO 9001
RTCA/D0160D: 1997	EN 46001
CISPR11:1997	21 CFR 820
JIS-T-100X-Series	ANSI/AAMI EC53:1995
Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1998	Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1993
Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD2-1998	European Active Medical Device Directive (93/42/EEC)

5) Intended Use:

The intended uses of the SonoSite™ Hand-Carried Ultrasound System, as defined by FDA guidance documents, are:

Fetal - OB/GYN	Musculo-skeletal (conventional)
Laparoscopic	Musculo-skeletal (superficial)
Intraoperative (abdominal organs and vascular)	Neonatal Cephalic
Abdominal	Pediatric
Small Organ (breast, thyroid, testicle)	Cardiac (adult)
Trans-vaginal	Cardiac (pediatric)
Trans-rectal	Peripheral Vessel

Typical examinations performed using the SonoSite™ Hand-Carried Ultrasound System are:

Abdomen: This system transmits ultrasound energy into the upper and lower quadrants of the abdomen of an adult or pediatric patient to obtain 2D, Color Power Doppler, PowerMap™ Directional Color Power Doppler, tissue harmonic, or PW Doppler images, which can be used to assess the presence and extent of some diseases and injuries.

Study of small parts and superficial structures including breasts, shoulders and other joints, thyroid, and superficial soft tissue: This system transmits ultrasound energy into the superficial soft tissue structures of the body to obtain 2D, Color Power Doppler, or PowerMap™ Directional Color Power Doppler images of normal structure and some pathologies of the breast, thyroid, superficial soft tissue, shoulder joints, wrist, ankle, and knee, which can be used to assess the presence and extent of some diseases and injuries.

Pediatric scans of organs, superficial structures, and bony structures: This system transmits ultrasound energy into the abdomen, pelvis and superficial structures of pediatric patients to obtain 2D, Color Power Doppler, PowerMap™ Directional Color Power Doppler, tissue harmonic, or PW Doppler images of the abdominal organs, great vessels, pelvic structures and pediatric hips, which can be used to assess the presence and extent of some diseases and injuries.

General cardiac studies in adults and pediatrics: This system allows the clinician to perform focused cardiac studies. This system transmits ultrasound energy into the thorax of adult and pediatric patients to obtain 2D, PowerMap™ Directional Color Power Doppler, M-mode, tissue harmonic, or PW Doppler images of the heart, great vessels, and anatomic and pathologic structures. This can be used to assess overall cardiac performance and size, determine the presence and location of fluid around the heart and lungs, aid in pericardialcentesis and pleuralcentesis procedures, and visualize blood flow through cardiac valves. Also, the system can be used to assess the presence and extent of some injuries and diseases.

Scans of the abdomen, cranium, pelvis and heart in neonates that weigh less than 1500 grams or are less than 32 weeks gestation: This system transmits ultrasound energy into the cranium, abdomen, pelvis soft tissue or heart of patients to obtain 2D, Color Power Doppler, PowerMap™ Directional Color Power Doppler, M-mode, or PW Doppler images. These images will be used to assess the presence and extent of some diseases or injuries. Some examples of the pathology that ultrasound is used for include: Cranium – hemorrhage, ischemia, shunt placement and dilated ventricles; Abdominal organs – renal disease, gallbladder disease; Pelvis – ovarian pathology, uterine pathology and testicular disease; Soft tissue/superficial tissue– hip, lymph nodes and superficial cysts.

GYN/Infertility: This system transmits ultrasound energy into the lower abdomen or vagina of a female patient to obtain 2D, Color Power Doppler, PowerMap™ Directional Color Power Doppler, M-mode,

tissue harmonic, or PW Doppler images of the reproductive system, which can be used to assess the presence and extent of disease in the female pelvic organs, monitor ovarian follicle size, and as an aid in chorionic villi sampling (CVS) procedures.

Obstetrics: This system transmits ultrasound energy into the abdomen or vagina of a pregnant woman to obtain 2D, M-mode, tissue harmonic, or PW Doppler images of a fetus, which can be used to estimate gestational age, number and weight, and assess the presence and extent of disease and confirm viability. Color Power Doppler or PowerMap™ Directional Color Power Doppler imaging is intended for high-risk pregnant women. High risk pregnancy indications include, but are not limited to multiple pregnancy, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

Prostate: This system transmits ultrasound energy through the prostate of an adult patient to obtain 2D, Color Power Doppler, or PW Doppler images of structures, which can be used to assess the presence and extent of disease or injury. Measurements are available to calculate the volume of the prostate gland.

6) Technological Characteristics:

This device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-Mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, Color Power Doppler, and PowerMap™ Directional Color Power Doppler) are the same as a combination of the predicate devices identified in item 3. Transducer patient contact materials are biocompatible.

This device conforms to the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA, 1998) for an on-screen display feature that provides information on potential thermal and cavitation bioeffect mechanisms. A user education program provides additional information so users may moderate the system's acoustic output in accordance with the ALARA (as low as reasonably achievable) principle.

The device's acoustic output limits are:

All applications:

I_{SPTA} (d)	720 mW/cm^2 (Maximum)
TIS/TIB/TIC	0.1 - 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)
I_{SPPA} (d)	0 - 700 W/cm^2 (Range)

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

SonoSite Inc.
C/O Mark Job, 510(k) Program Manager
TUV Product Service
1775 Old Highway 8 N.W.
Suite 104
NEW BRIGHTON MN 55112-1891

Re: K010374
Trade Name: SonoSite Hand-Carried Ultrasound System
Regulatory Class: II/21 CFR 892.1550/CFR 892.1560
Product Code: 90 IYN/90 IYO
Dated: January 26, 2001
Received: February 7, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoSite Hand-Carried Ultrasound System, as described in your premarket notification:

Transducer Model Numbers:

ICT/7-4 7.0-4.0 MHz Intracavitary Transducer
L38/10-5 10.0-5.0 MHz Linear Array
C60/5-2 5.0-2.0 MHz Curved Array
C15/4-2 4/0-2.0 MHz Curved Array
C11/7-4 7.0-4.0 MHz Curved Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded. The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small

Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: **SonoSite™ Hand-Carried Ultrasound System**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	N			B+M; B+PWD	Note 1
	Abdominal	P	P	N			B+M; B+PWD	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	N			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	N			B+M; B+PWD	Note 1
	Pediatric	P	P	N			B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	N			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	N			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal	P	P	N			B+M; B+PWD	Note 1
	Trans-vaginal	P	P	N			B+M; B+PWD	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	N			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	N			B+M; B+PWD	Note 1
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	N			B+M; B+PWD	Note 1
	Cardiac Pediatric	P	P	N			B+M; B+PWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	N			B+M; B+PWD	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010374

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite™ Hand-Carried Ultrasound System

Transducer: ICT/7-4 7.0-4.0 MHz Intracavitary Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	**N**			B+M; **B+PWD**	Note 1
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	**N**			B+M; **B+PWD**	Note 1
	Trans-vaginal	P	P	**N**			B+M; **B+PWD**	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010374

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite™ Hand-Carried Ultrasound System
Transducer: L38/10-5 10.0-5.0 MHz Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	**N**			B+M; **B+PWD**	Note 1
	Abdominal	P	P	**N**			B+M; **B+PWD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	**N**			B+M; **B+PWD**	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	**N**			B+M; **B+PWD**	Note 1
	Pediatric	P	P	**N**			B+M; **B+PWD**	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	**N**			B+M; **B+PWD**	Note 1
	Neonatal Cephalic	P	P	**N**			B+M; **B+PWD**	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	**N**			B+M; **B+PWD**	Note 1
	Musculo-skel. (Superfic.)	P	P	**N**			B+M; **B+PWD**	Note 1
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	**N**			B+M; **B+PWD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	**N**			B+M; **B+PWD**	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

David C. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010374

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite™ Hand-Carried Ultrasound System
Transducer: C60/5-2 5.0-2.0 MHz Curved Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	**N**			B+M; **B+PWD**	Note 1
	Abdominal	P	P	**N**			B+M; **B+PWD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	**N**			B+M; **B+PWD**	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	**N**			B+M; **B+PWD**	Note 1
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	**N**			B+M; **B+PWD**	Note 1
	Cardiac Pediatric	P	P	**N**			B+M; **B+PWD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

David G. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010374

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite™ Hand-Carried Ultrasound System
Transducer: C15/4-2 4.0 – 2.0 MHz Curved Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	**N**			B+M; **B+PWD**	Note 1
	Abdominal	P	P	**N**			B+M; **B+PWD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	**N**			B+M; **B+PWD**	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	**N**			B+M; **B+PWD**	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	**N**			B+M; **B+PWD**	Note 1
	Neonatal Cephalic	P	P	**N**			B+M; **B+PWD**	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	**N**			B+M; **B+PWD**	Note 1
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	**N**			B+M; **B+PWD**	Note 1
	Cardiac Pediatric	P	P	**N**			B+M; **B+PWD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	**N**			B+M; **B+PWD**	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

David A. Ayerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010374

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: SonoSite™ Hand-Carried Ultrasound System
Transducer: C11/7-4 7.0 – 4.0 MHz Curved Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	E	E	N			B+M; B+PWD	Note 1
	Intra-operative (Abdominal organs and vascular)						B+M	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	N			B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic	E	E	N			B+M; B+PWD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	E	E	N			B+M; B+PWD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	N			B+M; B+PWD	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy.

Prescription Use (Per 21 CFR 801.109)

David C. Legeman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010374